

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims,
corrected in response to the Notice of
Non-Compliant Amendment dated June 28, 2005

Page 1 of 16

Enclosure No. 2

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,377	08/28/2000	Sergey Matasov		9553

United States Patent and Trademark Office
Commissioner for Patents
Art Unit 3739
Examiner Mr. Leubecker, John P.
P.O. Box 1450, Alexandria VA 22313-1450
United States of America

EXAMINER	
LEUBECKER, JOHN P	
ART UNIT	PAPER NUMBER

3739

DATE MAILED: August 5, 2005

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

Endoscope with disposable cartridges for the invagination of endoscope endoscopic tube.

Description of invention.

This is the continuation of application PCT/LV98/00008 based on the priority applications P-97-190 from 03.10.97 (LV) and P-98-188 from 23.09.98 (LV).

BACKGROUND OF THE INVENTION.

1. Field of the invention.

The invention relates to the field of medicine, namely to colonoscopy and enteroscopy, but can also be used for industrial endoscopes.

2. Description of Background Art

The common feature of the endoscope, proposed in present application and of endoscopes according to known patents is a tube, eversible under fluid pressure. The inflated and everted tube invaginates an endoscope tube into explored channel and therefore was named by me as invaginator. The exploitation of invaginator is effective in case when it everts close to the objective and does not cover the latter.

The fluid pressure causes not only inflation and eversion of invaginator, but also its tight engagement with the endoscope tube. As a result of this engagement an everted part of invaginator becomes twice shorter than the endoscope tube.

U.S. Pat. 4,324,915 to Leighton et al., U.S. Pat. 4,616,331 to Kramann and U.S. Pat. 5,250,384 to Bob et al., whose disclosures are incorporated herein by references, illustrate the attempts to overcome the effect of invaginator's engagement with an endoscope tube.

Invaginator according to the US Pat. 4,324,915 is mono-layered. To remove the double lag of invaginator there is suggested by the periodical change of pressure and vacuum and by extracting of endoscope tube till the moment when its objective coincides with the place of invaginator's eversion. But the investigated

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims,
corrected in response to the Notice of
Non-Compliant Amendment dated June 28, 2005

Page 2 of 16

Enclosure No. 2

channel is tortuous and invaginator is a thin-walled tube. As a result together with the endoscope tube will be extracted also the invaginator. It seems to be complicated also the coincidence of objective together with the place of invaginator's eversion.

Is known the device under U.S. Pat. 4,615,331 from Oct. 7, 1986 to Kramann, comprising an endoscopic tube encased in an eversible elastic thin-walled tube which functions as a transporter-invaginator (hereinafter - invaginator) of the endoscopic tube. In the device according to US Pat. 4,615,331 invaginator is placed on the endoscope tube by long overlying parallel layers. The invaginator in the device according to this patent is set in long layers parallel to the transported tube. In this connection the place of invaginator's eversion periodically moves away from the objective. The more important defect of multi-layered invaginator is inconsequent unreeling of its layers. The premature eversion of lower layer will exclude or complicate eversion of others. One of the drawbacks of this device is the inconsistent unreeling of invaginator's layers, which is caused by their "sticking together" under air pressure and inevitable getting of air into spaces between them. Untimely eversion of any layer excludes from participation in intubation process the other layers, located above the everted one.

In the device according to US Pat. 5,250,384 the end of uneverted part of invaginator is attached to a chamber, which is an extra-organ storage of the supply portion of invaginator. The problem of engagement of the uneverted part of invaginator with the endoscope tube authors of US Pat. 5,250,384 propose to solve by feeding of working pressure into the uneverted part of invaginator. The working fluid pressure according to data of Grudt, Bob and Bob is varying from 0,4 till 1,2 bar (see US Pat. 5,585,938), but the uneverted part of invaginator, in spite of declaratory authors' assurance, inevitably communicates with the intestinal cavity. It is known that bursting of intestine starts at pressure of 0,17 bar and it bursts under the pressure of 0,235 bar (see www.anastomes.nared.ru/ourresult.htm). In addition to safety problem the US Pat. 5,250,384 does not solve the problem of displacement of invaginator's uneverted part from chamber to objective.

Thus, all known endoscopes with invaginator are insufficiently effective or dangerous.

Is known also the intestinal endoscope under the inventor's certificate SU 1522463 from 0000-00-00 to Matasov with an invaginator set in pleats and placed at the right angle with an endoscopic tube transported by the invaginator. This endoscope is used as a basis to the present invention and has been taken as a closest prior art. The endoscope according to the closest prior art comprises: - a light source; - a source of excessive pressure; - an endoscopic tube with an eyepiece, a control block having a communication branch-tube and a stop for a spring; - an invaginator of endoscopic tube consisting of an uneverted part encased in an everted part, at that the uneverted part of invaginator tightly adjoins the endoscopic tube and is placed in pleats perpendicularly to it. From the side of the uneverted end the invaginator is supported by a spring and the area of transition of the uneverted part of the invaginator into the everted part is limited by a tip (in the meaning of the "tip cover") of the endoscopic tube. Furthermore, the endoscope according to the closest prior art comprises: - an external seal of the endoscopic tube to which the end of the everted part of the invaginator is fixed; - rings on the uneverted end of the

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims,
corrected in response to the Notice of
Non-Compliance Amendment dated June 28, 2005

Page 3 of 16

Enclosure No. 2

invaginator. - an air-duct with a cock for feeding working pressure into the cavity of the everted part of the invaginator. - an anal dilator. Endoscopic tube of the closest prior art comprises light and image transmission elements, biopsy channels, channels for gas or liquid supply, and, in addition, comprises two pairs of close-coiled springs with traction lines which are pair-wise connected to the distal ring of a mechanism for bending a distal end of the endoscopic tube and rollers located in the control block and designed for manual extraction of traction lines.

The first drawback of the endoscope according to the closest prior art is unreliable operation of its invaginator resulting in difficulties with introduction of the endoscopic tube into the external seal (see lines 42-53 of the SU 1522466). The invaginator is to be everted under the tip, but during invagination the distal part of the endoscopic tube becomes bared. It can happen because of absence of a gap between the endoscopic tube and the uneverted part of the invaginator and because of a flabby structure of the latter, which cause the invaginator to adhere to the endoscopic tube under the air pressure. Tube kinks formed while bending the distal end also prevent free movement of the invaginator along the endoscopic tube. As a result, the spring is unable to displace the invaginator toward the tip. In addition, the uneverted end of the invaginator, connected with two rings, does not ensure sufficient pressurization of the cavity of the everted part of the invaginator.

The endoscope tube together with invaginator repeat all curves of explored channel. But bending of tube distal end is possible only till the definite number of curves. This is the second drawback of existing colonoscopes. Tube's end is bent by rotating of two rollers each connected to its pair of traction lines. Springs, comprising traction lines, on the distal end are continued by channels in the wall of cardan-jointed rings. Ends of traction lines are soldered to the distal ring of the cardan-executive mechanism for bending the tube distal end. Outward extraction of traction line from the spring decreases gaps between cardan rings thus forming a small radius of a curve. The second drawback of known endoscopes is that it is not possible to bend its distal end after the number of turns of an endoscopic tube has exceeded certain specific value. Its end is bent by rotation of two rollers each connected to its pair of traction lines. These traction lines are enclosed in springs, and the distal ends of springs are extended by channels in the wall of cardan-joined rings. Ends of traction lines are soldered to the distal ring of the cardan mechanism for bending of the distal end of the tube. Pulling a traction line out of a spring decreases gaps between cardan rings and forms a small radius of a turn. At that, the distal cardan ring pulls the opposite traction line in distal direction, thus ensuring an increase of space thereby increasing the gaps between rings. Difference of lengths of big and small half-circumferences of the tube's curve turn is a product of "π" and diameter of an endoscope endoscopic tube. Japanese authors point out that when 3-4 loops are formed, the distal end of an endoscope is blocked, but while biopsy forceps continue to function. This difference is explained by L. Atar formula

$$\frac{Q_1}{Q_2} = e^{a/f}$$

Application Number: 09/509,377

Date: August 5, 2005

Substantive specification & Listing of claims,
corrected in response to the Notice of
Non-Compliant Amendment dated June 28, 2005

Page 4 of 16

Enclosure No. 2

where: " Q_1 " - manual power realizing traction lines extraction force extracting the traction line; " Q_2 " - remaining from " Q_1 " power, attached to force applied to a distal cardan ring or to the cutters of biopsy forceps; " e " - basis of natural logarithm; " α " - traction line rotations in radians; " f " - friction index between a traction line and a spring. Under fixed values " Q_1 " and " f ", value " Q_2 " depends on value " α ", notice that for two consecutively connected a pair of consecutively joined traction lines of an endoscope the latter the value " α " is twice as large as for one traction line of biopsy forceps.

The third drawback of known endoscopes of the prior art is the problem of its maintenance. For recurrent use, an endoscope needs to be washed, disinfected and sterilized. However, there are reported cases of infecting patients with AIDS and other infectious diseases after endoscopy. Preparation of the endoscope according to the closest prior art for work requires its assembly. There are 10 detachable parts needed to be assembled in the endoscope according to the closest prior art, and its assembly takes about half an hour. Ergonomics of operating the existing endoscopes also complicates its mastering. Thus, the left hand holds the control block, switches on and off its cocks, rotates handles, which bend and fix the distal end of the tube, while the right hand introduces the tube into the intestine.

It has been practically proved proven in practice, that if endoscope has makes more than 3-4 loops, it is impossible to introduce biopsy forceps into it and to take a biopsate. This is the fourth drawback of the prototype prior art.

SUMMARY OF THE INVENTION.

The invention mainly pertains to the field of medicine and particularly is intended for the early diagnostics of colon cancer.

The objectives of the invention have been following: - ensure to increase reliability of investigation and easiness of introduction of an endoscopic tube into colon or others long flexuous channels; - to ensure bending of its distal end in flexuous channels; - to make maintenance of an endoscope more convenient; - to perform biopsy in flexuous channels. Implementation of said objectives will make colonoscopy available to any physician and will make it easier for experienced endoscopists.

As the base for all variants of the construction of present invention serves an endoscope with invaginator, whose unevented end is coupled with the distal part of endoscope tube, at that the invaginator is made by plates and in compact state is held on said distal part.

In the simplest variant of present invention, the unevented part of invaginator is enclosed into the evented one, and the end of the evented part is fixed on a seal of endoscope tube and connected to fluid pressure.

In preferred embodiments of present invention the invaginator is made in the form of hollow compact flexible cylinder which has a gap with a preservative of the distal part of endoscope tube. A compact hollow cylinder of the invaginator is formed of tightly compressed in longitudinal and transverse directions plates of different forms of an overable elastic tube placed at any angles with the longitudinal axis of an

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims
corrected in response to the Notice of
Non-Compliant Amendment dated June 28, 2005

Page 5 of 16

Enclosure No. 2

endoscope tube. For its flexibility the cylinder could have recurrent narrowings of an external diameter and widenings of its internal diameter.

These objectives have been achieved by the fact that the construction of an endoscope consisting of: - a source of light; - a source of pressure; - biopsy forceps; - an endoscopic tube with the control block and communication branch, at that the endoscopic tube comprises internally elements for light and image transmission, a channel gas/liquid, a biopsy channel, two pairs of springs with traction lines, which pair-wise connect the mechanism for bending the distal end of the endoscopic tube with manual extractors of traction lines located in the control block, and externally - a compressed spring placed on tubes distal end, an invaginator, a tip, a mobile seal, an anal dilator, has been further supplemented with:

- a disposable cartridge for the invagination of an endoscopic tube;
- a system of extractors-intractors of traction lines;
- an essentially changed endoscopic tube;
- a system of introduction and extraction of biopsy forceps;
- an intensifier of traction line of biopsy forceps.

Preferred embodiments of present invention comprise a disposable sterile cartridge for the invagination of endoscope tube, the cartridge could comprise: The safety of introduction into the intestine and convenience of exploitation of the suggested endoscope is in the first turn ensured by the disposable sterile cartridge which consists of: - a shell which has with a projection at its proximal end, wherein could be enclosed are comprised: a preservative of the distal part of the endoscope endoscopic tube, which could be joined at the proximal end to a spring stop which preservative is united with a spring stop on its proximal end; a compressed spring; a spring distancer in which wherein ((a)) the distal seal of the endoscopic tube is located, which seal is coupled to fastened to an uneverted end of invaginator; a fixator of said compressed spring; an invaginator in the form of a compact hollow flexible cylinder, which has a gap with said preservative and could comprise a recurrent narrowings of ((an)) its external diameter and widenings of its internal diameter, at that the same time the everted end of the invaginator is fastened on the distal end of the shell; - a proximal seal of the endoscope endoscopic tube fastened on the distal end of said shell, which seal is joined with the shell; - an anal dilator having with a channel in its wall; - a tip of endoscope endoscopic tube coupled united with the distal end of said preservative, which one (the tip) tip has a protective glass, a channel for washing of glass and blowing of intestine for inflation of intestines, an element elements for hermetic joining to the endoscope endoscopic tube. The compact hollow flexible cylinder of the invaginator is formed of crumpled and tightly compressed in longitudinal and transverse directions variform pleats of an eversible thin-walled tube, placed at different angles with the longitudinal axis of the endoscopic tube. In preferred embodiments of present invention Moreover, the cartridge for invagination of the endoscope endoscopic tube could be attached to is joined with a mechanism for its introduction of said tube. The mechanism for introduction could comprise which mechanism is made in the manner of a cylinder with two pistons, which are interconnected by distancers and segment of an elastic tube, but a and the cavity between them through a pedal cock communicates with fluid pressure communicates with a source of gas pressure through a pedal cock, but a at that the cavity between ((a))

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims,
corrected in response to the Notice of
Non-Compliance Amendment dated June 28, 2005

Page 6 of 16

Enclosure No. 2

the proximal seal of the endoscope endoscopic tube and ~~((a))~~ the distal piston comprises encloses a spring, which returns pistons to their home position and through the pedal cock communicates with fluid pressure a source of vacuum.

~~In preferred embodiments of present invention the inserted endoscope tube could comprise for coupling with cartridge: an internal transverse plate of its distal cover, which raise tube's flexibility; two air ducts, where the larger one has a lateral opening into a cavity of the proximal seal of the disposable cartridge for invagination, but the smaller one into a cavity of distal and proximal preservatives; an area for hermetic fixation of ends of preservatives; a proximal preservative. At that a control block could be made as a desk unit, but the cock, which feeds the working pressure into the everted part of invaginator could be placed in pedal.~~

~~In preferred embodiments of present invention the system for banding of the distal end of endoscope tube in tortuous channels could comprise the sources of fluid pressure. The system of extractors-injectors of traction lines has a pneumo-hydro-manual drive and creates additional force equal to a few grams at the distal end of the traction lines. The system comprises sources of excess pressure and vacuum connected to cavities of elastic tubes. The elastic tubes could comprise which cavities contain liquid and springs with traction lines, at that said tubes could be are fixed to said springs ~~((by))~~ with a thread. ~~((but))~~ and the springs could be executed with pitch are made with spacings and are finished on some distance from an executing mechanism for banding the distal end, at that said traction lines on the distal end could be joined are connected with springs, and in the control block the traction lines are attached to manual extractors-injectors of traction lines connected united with elements ensuring which ensure synchronous fluid evacuation from the cavity of manually extracted traction line and fluid feeding into the cavity of introduced traction line feeding of vacuum into the cavity of manually extracted traction line and feeding of excess pressure into the cavity of an introduced traction line. In order to create the additional force the distal end of the tube and of the traction line could be finished is possible to finish by a cylinder and a piston, or the tube could be finished it is possible to finish the tube by an elastic element, for example a siphone, ~~((but a))~~ and the traction line could be connected to connect with siphone's distal end. ~~((A))~~ Manual extractors-injectors of the traction lines could be made in ~~((the))~~ a manner of a rod, ~~((but))~~ and the sources of fluid pressure and vacuum - in ~~((the))~~ a manner of a piston and a cylinder, positioned on the rod. An element, ensuring which ensures synchronous fluid evacuation from feeding of vacuum into the cavity of the extracted traction line and fluid feeding pressure into the cavity of the introduced traction line, could be made as a pinion a gear mated with cogs of two rods. As each of two pinions gears is coupled only with its pair of traction lines, that is why the banding of the tube's end could be is performed in two stages. The cross-piece crosspiece with a management an operating lever, wherein where the central part of the crosspiece is movably connected with the body of the control block, ~~((but))~~ and the ends of the crosspiece are attached to four rods, could ensure ensures simultaneous banding of the tube's end in any direction.~~

Application Number: 09/509,377

Substantive specifications & Listing of claims,
corrected in response to the Notice of
Non-Compliance Amendment dated June 28, 2005

Page 7 of 16

Date: August 5, 2005

Enclosure No. 2

A novel endoscopic tube is supplemented with: - an internal transverse plate of its external cover, - two air ducts, where the larger one has a lateral opening into the cavity of the proximal seal of the cartridge for lavigation, and the smaller one - into the cavity of distal and proximal preservatives, - means for hemostatic fixation of preservatives' ends; - a proximal preservative. In addition, the control block of the endoscopic tube could be made in the distal manner, and the cock, which leads the working pressure into the expanded part of lavigator, could be placed in the pedal.

In preferred embodiments of present invention in order to conduct biopsy in distal channels, the insertion and extraction of biopsy forceps could be realized with a help of fluid pressure. Pneumo-hydraulic manual system for introduction and extraction of biopsy forceps consists of pressure and vacuum sources, which are connected through a cock to the cavity of (the) a biopsy channel, the entrance to which is sealed (by) with a seal of biopsy forceps, and at the distal end of which there is the distal end of said forceps has a piston of the biopsy channel.

At least the biopsy forceps comprises the biopsy forceps with a pneumo-hydraulic extensor of insertion line comprises a flexible hemostatic tube, which is connected to source of fluid pressure with sources of pressure and vacuum, (the) and the distal end of the tube and the traction line could be fixed (clamped) with a cylinder and a piston. The said cylinder piston is possible to replace with a segment of capitan, the end of which is connected to traction line.

The subject of present invention is an endoscope, comprising:

- an invaginator whose unwinded end is coupled with the distal part of the endoscope tube, of that said invagination is held on said distal part of the endoscope tube;
- an invaginator formed of plate, tightly compressed in longitudinal and transverse directions to a compressed hollow cylinder, which has a gap with said distal part of the endoscope tube.

The subject of present invention also is an endoscope with a disposable cartridge for the invagination of endoscope tube, the cartridge comprises invaginator whose unwinded end is coupled with the distal part of the endoscope tube, said invaginator is formed of plate, tightly compressed in longitudinal and transverse directions in a compressed hollow cylinder, which has a gap with said distal part of the endoscope tube and is held on said distal part.

Each foregoing subjects of invention could also comprise:

- a said cylinder of invaginator having a diameter of external diameter and midways of internal diameter;
- a shell for conducting fluid fluid part of endoscope tube with invaginator along inside, of that the diameter of said shell is compressed in the direction of said invagination;
- sliding ends of endoscope tube, including a cavity of the cavity part of invaginator;
- an anal channel;
- said anal channel with a channel in its wall;

Application Number: 09/509,377

Date: August 5, 2005

Substantive specification & Listing of claims,
corrected in response to the Notice of
Non-Compliant Amendment dated June 28, 2005

Page 8 of 16

Enclosure No. 2

- ~~o a spring of invaginator,~~
- ~~o a preservative of the distal part of endoscope tube united with tube's tip, at that the proximal end of preservative and the tip have areas for hermetic fixation to the distal part of said endoscope tube;~~
- ~~o said tip comprises a protective glass and communicates with intestinal cavity;~~
- ~~o a mechanism for introduction of the endoscope tube which is a cylinder-piston unit having a hermetic cavity, confined by a cylinder, a piston and a segment of an elastic tube connected to fluid pressure;~~
- ~~o an endoscope tube with an transverse pleats of its external cover, which are directed internally;~~
- ~~o an endoscope tube with distal drives of traction lines banding its distal end, which are springs executed with pitch and enclosed inside elastic tubes connected to fluid pressure;~~
- ~~o an endoscope tube with distal drives of traction lines banding its distal end, which are cylinder-piston units connected to fluid pressure;~~
- ~~o an endoscope tube with distal drives of traction lines banding its distal end, which are syphons connected to fluid pressure;~~
- ~~o an endoscope tube with a biopsy channel connected to fluid pressure and a biopsy forceps which are flexible hermetic tube with a biopsy channel's piston on tube's distal end;~~
- ~~o said biopsy forceps having a distal drive of forceps which is a cylinder-piston unit connected to fluid pressure;~~
- ~~o said distal drive of forceps which is a syphon connected to fluid pressure.~~

The subject of invention also is a method of prophylaxis from getting infected of endoscope tube and patient, the method comprises:

- ~~o hermetic connection of endoscope tube to tube's distal part preservative and to a tip united with said preservative, having a protective glass and communication with intestinal cavity;~~
- ~~o hermetic connection of said preservative to the unworked end of invaginator of endoscope tube, which is an elastic tube everted under fluid pressure, the elastic tube is formed by pleats in a compact hollow cylinder which has a gap with said preservative;~~
- ~~o feeding of fluid pressure through a channel in endoscope tube under the protective glass of said tip.~~

BRIEF DESCRIPTION OF THE DRAWINGS.

The graphic materials explain clarify the essence of invention, where on the FIG.1 represents a variant of is represented the endoscope with disposable cartridge for invagination, where wherein: a - a handle-shaped control block; b - distal part of the endoscope tube with mounted cartridge; c - longitudinal section of the cartridge; d, e, f - enlarged fragments of FIG.1c. On FIG. 2 is shown represented the system of extraction-introduction of traction lines with a fluid-manual pneumo-hydro-manual drive, in case when the distal end of the endoscope is in direct position, where wherein: a - position a state of system elements comprised in the control block; b - enlarged fragment of FIG. 2a; c - distal part of (tube) the endoscope with "bared" system elements (vertical arrows show the top-bottom of endoscope the endoscopic tube); d

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims,
corrected in response to the Notice of
Non-Compliant Amendment dated June 28, 2005

Page 9 of 16

Enclosure No. 2

— enlarged fragment of FIG. 2c. On FIG. 3 is represented the system of extraction-intracation of traction lines when the end of of ((an)) the endoscope is bent downwards, where wherein: a - position a state of elements contained comprised in the control block; b - enlarged fragment of FIG. 3a; c - distal part of the endoscope endoscopic tube with "bared" elements (horizontal arrows show the driving direction of the traction lines motion); d, e - enlarged fragments of FIG. 3a. On FIG. 4 are represented: a - a design of new endoscope; b - a crosspiece with a lever ((for)) bending the distal end of endoscope in any direction; c - a construction of a mechanism for introduction of the endoscope endoscopic tube; d - a system of introducing and extraction extraction and intracation of biopsy forceps. On FIG. 5 is represented the simplest variant of present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS.

The list of numerical markings of FIG. 1-5 Specification of numerical markings of FIGs. 1-4 is given at the end of the specification description.

A simplest variants of present invention could comprise (see FIG. 5): — a source 5 of excessive pressure; — an endoscope tube 3 with a control bloc 2 having a communication branch, a stop 11 for spring 10; — an invaginator of endoscope tube 3 which consists of everted part 4 and uneverted part enclosed in said part 4, at that the uneverted part of invaginator tightly adjoins to an endoscope tube and is placed by pleats perpendicularly to it. From the side of an uneverted end 7 the invaginator is supported by spring 10, but the place of transition of uneverted part of invaginator into its everted part 4 is limited by tip 6. Besides, the endoscope prototype comprises: — an external (proximal) seal 13 of tube 3 on which the end 12 of the everted part 4 of invaginator is fixed by a ring 16; — rings 8, 9 on the uneverted end 7 of invaginator; — an air duct 15 with a cock 17 for feeding of working pressure into a cavity 14 of the everted part 4 of invaginator; — an anal dilator 19.

The invaginator is to be everted under tip 6, but during the process of invagination the distal part of tube 3 becomes bared. It could happen both due to absence of gap between tube 3 and uneverted part of invaginator and to a friable structure of said uneverted part, which under the action of air pressure engages to tube 3.

The problem of engagement of the uneverted part of invaginator with the endoscope tube 3 was solved by invaginator formed of plate tightly compressed in longitudinal and transverse directions in a compact hollow cylinder 23 (see FIG. 2), the cylinder has a gap 25 with the distal part of an endoscope tube 3 and for its flexibility could have a recurrent narrowings of external diameter and widenings of its internal diameter respectively.

Further follows more complicated variants of present invention (see FIG. 2, FIG. 3, FIG. 4) comprising A novel endoscope includes an endoscope endoscopic tube 3 with a control block 2 and a communication branch. There are possible, for example, a following constructions. An air duct 15 and a cock 17 positioned on the control block 2 or in a pedal, connect a source of fluid working pressure with an opening

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims,
corrected in response to the Notice of
Non-Compliant Amendment dated June 28, 2005

Page 10 of 16

Enclosure No. 2

21 into the cavity of a seal 13, which cavity communicates with a cavity 14 of a shell 22. The distal part of the shell 22 is commensurable by length and diameter in relation to the uneverted part of an invaginator 23, but the and its proximal part - to a compressed spring 10. The everted end 12 of the invaginator 23 is connected to fastened on the shell 22 by a ring 16. The invaginator 23 has narrowings and widenings 24, as well as a gap 25 with a distal preservative 26 at that the gap 25 is keeping also at working pressure in the cavity 14. Ends of the distal 26 and a proximal 27 preservatives and as well as corresponding to them places of the tube 3 have areas 28 for interconnection and hermetization. A seal 29 on the end 7 of the invaginator 23 separates the cavity 14 from the cavity 25, which communicates with the intestinal cavity. A distancer 30 prevents deformation of the seal 29 by the spring 10. Ends of compressed spring 10 are based rested on the distancer 30 and a stop 11 at the end 26 of the preservative 26. The stop 11, in its turn, is positioned on ((the)) a projection 31 of the shell 22. The distal end of the preservative 26 ends with finishes by a tip 6 with channels 32 for washing of a protective glass 33 and blowing-up inflating of intestines, as well as and with an element for connection fixation to the endoscope endoscopic tube 3. On the border ((of)) between narrow and broad wide parts of the shell 22, there is an area ((of)) with an intermediate diameter, with indented wherein is pressed an elastic ring 34 for fixation of the compressed spring 10. A channel 35 in an anal dilator 19 is used for decompression of intestines during intubation. In the tube 3, besides the enumerated in addition to afore-enumerated, there are elastic tubes 36, 37 comprising springs 38, 39 and traction lines 40, 41. The tubes 36, 37 are connected to the springs 38, 39 with a thread 42. Near to a mechanism 43 for bending of the distal end of the tube 3, the ends of the tubes 36, 37 are closed with plugs 44, which plugs also connect the springs 38, 39 with the traction lines 40, 41. Proximal ends of tubes 36, 37 are connected with sources 45 of fluid excess pressure and vacuum. Proximal ends of the traction lines 40, 41 are connected with their manual extractors-intractors 46, but the latter and said extractors-intractors - with an element 47, which ensures synchronous evacuation of fluid from feeding of vacuum into the cavity of the extracted traction line 40 and feeding of fluid of pressure into the cavity of the introduced traction line 41.

Endoscope The endoscopic tube 3 has ((an)) internal pleats 48 of its external cover, an air-duct 49 with two openings 50, designed which serve for vacuum fixation of the preservatives 26, 27 to the tube 3; and also additionally the tube 3 has a removable sleeve gasket 51. The control block 2 has a cock 52 of ((an)) the air-duct 49. The seal 13 is hermetically connected to a mechanism 53 for introduction of the endoscope endoscopic tube 3. ((A)) The mechanism 53 for introduction of the tube 3 is operated by a pedal 54 ((but)) and a lever 55 realizes controls the bending of tube's end. A cylinder 56, two pistons 57, distancers 58 and segment of an elastic tube 59 confine limit a cavity 60, which is connected with a source of fluid pressure by means of a cock in the pedal 54. A cavity 61 comprises a return spring 62 and is connected with a source of fluid pressure vacuum by means of a cock in the pedal 54. A seal 64 and a nut 65 are mounted on biopsy forceps 63, but piston 63 is positioned at their distal end while at the distal end of said forceps a piston 66 is positioned. Seal for the seal 64 and the nut 65 is located at entry 67 to the biopsy channel, which is positioned with cock 68 on control block 2 which entry as well as a cock 68 are positioned on control block 2. A siphona 69, which serves as a source of fluid pressure and vacuum

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims,
corrected in response to the Notices of
Non-Compliant Amendment dated June 28, 2005

Page 11 of 16

Enclosure No. 2

in ~~((the))~~ a pneumatic intensifier of traction line of biopsy forceps, could be combined with ~~((its))~~ a handle of biopsy forceps 83.

Marks made on the preservative 27 and the tube 3 serves serve for their correct positioning connection. ~~((Then))~~ After that the mechanism 53 is mounted on the tube 3 and the cartridge for invagination is fixed. Pressing on the cock 52 will ensure the vacuum fixation of the preservatives 28, 27 to the tube 3. After introduction of the seal 13 into the cylinder 58, endoscope's preparation for work is completed.

After the patient has been placed on an endoscope-endoscopic table, ~~((a))~~ the cartridge is oiled and introduced into the rectum and its ampoule is examined as if with a rigid rectoscope. The pressure in the cavity 14 is fed by increased by pressing the cock 17 thus releasing freeing the distancer 30 from coupling with the flexator 34 and the shell 22. Thereby Thus, the spring 10 is released and it is possible to proceed with invagination of the tube 3. Eversion of the invaginator 23 and introduction of the tube 3 into the colon occurs under fluid working pressure in the cavity 14 at moments of pressing pedal 54 when the pedal 54 is pressed. During In the course of the endoscopy procedure the intestines are to be distended inflated. Gas into intestines is constantly supplied through a gas/liquid channel in the tube 3 and further through the channel 32 of the tip 6 thus preventing penetrating ingress of intestinal contents under ~~((a))~~ the protective glass 33. Gas evacuation from intestines occurs through ~~((a))~~ the channel 35 of the anal dilator 19.

Bending of the mechanism 43 is realized by means of fluid-pressure the sources 45 of excessive pressure and vacuum, by manual extractors-intractors 46 of traction lines 40, 41 and by means of elements 47 which ensure evacuation of fluid from the tube 36 feeding of vacuum into the cavity of the tube 38 which comprises the extracted traction line 40, and feeding of fluid of excessive pressure in the cavity of the tube 37 containing which comprises the introduced traction line 41. As a result of fluid evacuation Under the action of vacuum the elastic tube 36 and the spring 38 are shortened. Considering, that their distal end is connected with the traction line 40, this shortening ~~((its))~~ relieves manual extraction of this traction line. Fluid-pressure Under the action of pressure in the tube 37 the latter this tube and the spring 39 elongates towards the executing mechanism 43 thus relieving manual intraction of the traction line 41. The thread 42 twisted on tubes 36, 37, connects them combines these tubes with the springs 38, 39. Thus, evacuation and feeding of fluid vacuum and pressure, which shorten and elongate the tubes 36, 37 and the springs 38, 39, ensure application of powers forces to distal ends of traction lines 40 and 41; manual extraction and intraction of the traction lines 40, 41, creates create synchronous efforts on their proximal ends of traction lines. The mechanism 43 of the tube 3 is bent downwards by the above-mentioned method. During bending of mechanism 43 upwards When the mechanism 43 is bent upwards, all above enumerated elements are moved in opposite directions; but bending of mechanism 43 to the left and to the right is implemented by the second pair of traction lines the second pair of traction lines, which work similarly, implement bending of the mechanism 43 to the left and to the right. In intermediate positions the mechanism 43 is bent by interchangeable application use of both pairs of traction lines. The

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims,
corrected in response to the Notices of
Non-Compliance Amendment dated June 28, 2005

Page 12 of 16

Enclosure No. 2

element 47 made in the shape of a crosspiece with the lever 55, ensures simultaneous banding of the mechanism 43 in any direction.

As during colonoscopy As now in the course of colonoscopy the tube 3 repeats all natural flexures of the colon, ~~((its))~~ tube's exubation must not be accelerated. The anal dilator 19, through which exubation is to be conducted, eliminates reduces to minimum unpleasant sensations caused by this process.

The most practically important version embodiment of the invention is a colonoscopy with the endoscope endoscopic tube 3 without biopsy channel. ~~((A))~~ The disposable cartridge ensures an available to all and atraumatic transportation of the tube 3 in the colon, preservatives 26, 27 protect the patient from infections seated in the endoscopic tube 3, and the tube 3 in its turn - from getting contagious during endoscopy. ~~The management ergonomics of~~ Ergonomics of operating with such colonoscopy also makes it available to any physician: during endoscopy a physician in sedentary position watches the screen, presses the pedal cock 17 with one foot and the pedal 54 with another, with the right hand controls the lever 55, and in case of necessity washes the protective glass 33 by pressing on the cock with the left hand. Such colonoscopy is necessary firstly for family doctors, gastroenterologists and surgeons for the regular screening of colon cancer screening. Having selected the "suspicious" patients, out-patient physicians will direct them to an in-patient clinic for conducting biopsy taking and other thorough examinations.

~~For realization of biopsy~~ For biopsy taking is used a cartridge with the tip 6, without the glass 33 is used. Having exhausted the possibility of manual insertion of the forceps 63, it is necessary by means of the seal 64 and the nut 65 to seal hermetically the entry 67 into the biopsy channel and connect it by means of the cock 68 to the source of fluid pressure. Further insertion of the forceps 63 is performed by their manual intraction and due to fluid liquid or gas pressure on the piston 66, but ~~extraction - while forceps'~~ extraction is performed by switching the cock 68 in the "vacuum" position and by manual extraction of the forceps 63. Due to location of the pressure and vacuum source 69 of fluid pressure of the traction line intensifier in the handle of said forceps, bioplate taking is made is implemented as previously - approach of rings ensures movement of the traction line inwards, but detachment - while rings' detachment - extraction of the traction line.

Specification of graphic materials' marks on FIG. 4-5 markings on fig. 1-4 is as follows:

- 2 - the control block with the communication branch tube;
- 3 - endoscope the endoscopic tube;
- 4 - everted part of invaginator (on FIG. 5 only);
- 5 - source of working pressure in cavity 14 (on FIG. 5 only);
- 6 - the tip of endoscope the endoscopic tube 3;
- 7 - the uneverted end of the invaginator 23;
- 8,9 - rings at the end 7 of invaginator (on FIG. 5 only);
- 10 - the compressed spring;

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims,
corrected in response to the Notice of
Non-Compliant Amendment dated June 28, 2005

Page 13 of 16

Enclosure No. 2

-
- 11 - the stop for the spring 10;
 - 12 - the everted end of the invaginator 23;
 - 13 - the proximal seal of the tube 3;
 - 14 - the cavity of the everted part 4 of the invaginator 23;
 - 15 - the air-duct for feeding of fluid working pressure into the cavity 14;
 - 16 - the ring, fixing the end 12 of the invaginator 23;
 - 17 - the cock of the air-duct 15;
 - 18 - manometer (on FIG. 5 only);
 - 19 - the anal dilator;
 - 20 - rectum (on FIG. 5 only);
 - 21 - air-duct 15 opening the opening of the air-duct 15 on the tube 3;
 - 22 - the shell of cartridge for invagination;
 - 23 - the invaginator formed into a compact flexible cylinder;
 - 24 - the narrowings and widenings of the cylinder of the invaginator 23;
 - 25 - the gap (cavity) between the cylinder of invaginator 23 and the preservative 26;
 - 26 - the distal preservative of the tube 3;
 - 27 - the proximal preservative of the tube 3;
 - 28 - the areas on the tube 3 and at the on the ends of preservatives 26, 27 for their hermetic connection;
 - 29 - the distal seal between the tube 3 and the end 7 of the invaginator 23;
 - 30 - the distancer between the spring 10 and the invaginator 23, comprising seal 29 which distancer comprises the seal 29;
 - 31 - the projection on the shell 22 for the stop 11;
 - 32 - the channel in the tip 6;
 - 33 - the protective glass of the tip 6;
 - 34 - the elastic ring, fixing the spring 10 in a compressed state;
 - 35 - the channel in the anal dilator 19;
 - 36 - the lower elastic tube of extractor-intractor of traction lines;
 - 37 - the upper elastic tube of extractor-intractor of traction lines;
 - 38 - the lower spring of extractor-intractor of traction lines;
 - 39 - the upper spring of extractor-intractor of traction lines;
 - 40 - the lower traction line of extractor-intractor of traction lines;
 - 41 - the upper traction line of extractor-intractor of traction lines;
 - 42 - the thread fixing the elastic tubes 36, 37 to the springs 38, 39;
 - 43 - the mechanism for bending of the distal end of the tube 3;
 - 44 - plug closing the plug, which closes the tubes 36, 37 and connects the springs 38, 39 with the traction lines 40, 41;
 - 45 - the sources of fluid pressure of pressure and vacuum;
 - 46 - the manual extractors-intractors of the traction lines 40, 41;
 - 47 - the element for extraction-intraction of one or two pairs of the traction lines;
 - 48 - the pleats of external cover of the tube 3;

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims,
corrected in response to the Notice of
Non-Compliant Amendment dated June 28, 2005

Page 14 of 16

Enclosure No. 2

-
- 49 - the air-duct into cavity of the preservatives 26, 27;
 - 50 - the distal and proximal openings of the air-duct 49 on the tube 3;
 - 51 - the sleeve gasket;
 - 52 - air-duct 49 cock the cock of the air-duct 49 on the control block 2;
 - 53 - the mechanism for insertion of the endoscope endoscopic tube 3;
 - 54 - the pedal for switching on the mechanism 53;
 - 55 - the lever of the element 47, made in a shape of a crosspiece;
 - 56 - the cylinder of the mechanism 53;
 - 57 - the pistons of the cylinder 56;
 - 58 - the distancers between the pistons 57;
 - 59 - segment of the elastic tube, attached to the pistons 57;
 - 60 - the hermetic cavity, enclosed by segment of the elastic tube 59 and the pistons 57;
 - 61 - the hermetic cavity, enclosed by the seal 13 and the distal piston 57;
 - 62 - the spring, returning the pistons 57 to home position;
 - 63 - the biopsy forceps;
 - 64 - the seal of the entry 67 into a biopsy channel;
 - 65 - the nut, fixing the seal 64;
 - 66 - the piston of the biopsy forceps;
 - 67 - the entry into a biopsy channel;
 - 68 - the cock, feeding the fluid pressure which feeds pressure or vacuum into a biopsy channel;
 - 69 - the source of fluid pressure of pressure and vacuum connected with the cavity of biopsy forceps 63;
 - 70 - the cutters of the biopsy forceps 63;
 - 71 - the distal intensifier (drive) of the traction line of the cutters 70.

Application Number: 09/509,377

Date: August 5, 2005

Substitute specification & Listing of claims,
corrected in response to the Notice of
Non-Compliant Amendment dated June 28, 2005

Page 15 of 16

Enclosure No. 2

LISTING OF CLAIMS.

Claim 1 (Currently amended): An endoscope with disposable cartridges for the invagination of endoscopic tube, comprising

- o an endoscopic tube (3) having a distal part nearest to tube's distal end with a guided distal end,
- o an invaginator of the endoscope tube, which is an elastic tube inflated and everted for invagination of the endoscope tube into the explored channel, said elastic tube is gathered by pleats and has an uneverted end,

wherein the improvement comprises an invaginator whose uneverted end is coupled with said distal part of the endoscope tube, at that said invaginator is held on said distal part of the endoscope tube.

- o a disposable cartridge located on the distal part of the endoscopic tube (3) and comprising an invaginator of the endoscopic tube, which invaginator is an eversible tube with an uneverted end (7) joined with the endoscopic tube (3), and an uneverted part of invaginator formed by pleats into a compact hollow cylinder (23), having a gap (25) with the distal part of the endoscopic tube (3).

Claims 2 and 3 (Canceled).

Claim 4 (Currently amended). The endoscope according to claim 2 or 3 1, wherein said the cylinder (23) of the invaginator has comprises narrowings (24) of its external diameter and widenings (24) of its internal diameter.

Claim 5 (Currently amended). The endoscope according to any of claims 1 to 3 claim 1, further comprising a shell for conducting the distal part of said endoscope tube with invaginator along retraction, at that the diameter of said shell is commensurate to the diameter of said invaginator, wherein the cartridge comprises a shell (22), which contains the cylinder (23) of the invaginator.

Claims 6-9 (Canceled).

Claim 10 (Currently amended). The endoscope according to any of claims 1 to 3 claim 1, further comprising wherein the cartridge comprises a preservative (23) of the distal part of the endoscopic tube (3), which preservative is united with a tip (6) of the endoscopic tube (3) at that the proximal end of preservative and the tip have areas for hermetic fixation to the distal part of said endoscope tube and comprises areas (28) for the hermetic fixation to the endoscopic tube (3).

Claim 11 (Currently amended). The endoscope according to claim 10 4, wherein the tip (6) comprises a protective glass (33) and communicates with a cavity of intestines.

Claim 12 (Currently amended). The endoscope according to any of claims 1 to 3 6, further comprising a mechanism (53) for introduction of the endoscopic tube (3) into the everted part of invaginator, which is a cylinder-pleter unit having a hermetic cavity, confined by a cylinder, a piston and a segment of an elastic